International Journal of Pharmaceutical Research and Applications
Volume 8, Issue 1 Jan-Feb 2023, pp: 1811-1820 www.ijprajournal.com ISSN: 2249-7781

A Review: Enteric Coated Tablets

Pragati Datta Sawalkar, Dr. V.G Rajurkar, Prof.V.S.Munde
Dr. VedPrakash Patil College Of Pharmacy, Aurangabad
Principal, Dr. Vedprakash Patil Pharmacy College.Georai Tanda, Paithan Road, Aurangabad
Shri dhaneshwari manav vikas mandals Dr.Vedprakash Patil Pharmacy College, Aurangabad.
2022-2023

Submitted: 05-02-2023 Accepted: 20-02-2023

ABSTRACT
Enteric coated tablets are solid unit dosage forms which are designed to bypass the stomach and release the drug in small intestine and are meant for oral administration. The word "enteric" indicates small intestine; therefore enteric coatings prevent release of medication before it reaches the small intestine. Most enteric coatings work by presenting a coated surface that is stable at the highly acidic pH found in the stomach, but breaks down rapidly at a less acidic (relatively more basic) pH. Materials used for enteric coatings include CAP, CAT, PVAP and HPMCP, fatty acids, waxes, shellac, plastics and plant fibers. The present review describes enteric coating, their ideal properties, benefits and limitation, various polymers used, their chemical structure, criteria for drug selection and mechanism, methods of manufacturing and evaluation of enteric coated tablets. Recently, these have attracted the interest of many formulators due to their advantages over the conventional drug delivery systems as they prolong the dosing intervals and also increase patient compliance. The study provides an overview of the recent advances that have taken place in this arena.

KEYWORDS—Enteric coated tablet, Evaluation, Ideal Properties, Mechanism and Methods of enteric coated tablets.

I. INTRODUCTION

Tablet is a pharmaceutical solid dosage form, comprising a mixture of active substances and excipients, commonly in powder form, pressed or compacted right into a stable. Coating is a process by which the coating material is applied to the surface of a dosage form in order to confer specific benefits to the dosage form. An enteric coating is a barrier that controls the release of oral medication in the stomach and promotes its release in the intestine where it is absorbed. The word "enteric" indicates small intestine; therefore enteric coatings prevent release of medication before it reaches the small intestine. The enteric coated polymers remain unionise at low pH, and therefore remain insoluble. But as the pH increases in theGIT, the acidic functional groups are capable of ionisation, and the polymer swells or becomes soluble in the intestinal fluid. Materials used for enteric coatings include CAP, CAT, PVAP and HPMCP, fatty acids, waxes, shellac, plastics and plant fibers.[1]

Enteric coating covers various ideal properties such as resistance to gastric fluids, susceptible/ permeable to intestinal fluid, compatibility with most coating solution components and the drug substrate, formation of continuous film, nontoxic, cheap and ease of application. Various polymers used in enteric coating are shellac (esters of aleurtic acid), cellulose acetate phthalate (CAP), Poly(methacrylic acid-co-methyl methacrylate), cellulose acetate trimellitate (CAT), poly(vinyl acetate phthalate) (PVAP) and hydroxypropyl methylcellulose phthalate(HPMCP). Polymers were selected based on the dissolution pH ranging from 4.5 – 7.0.[2]

TABLET COATING

Coating is a process by which an essentially dry, outer layer of coating material is applied to the surface of a dosage form in order to confer specific benefits that broadly ranges from facilitating product identification to modifying drug release from the dosage form. After making a good tablet, one must often coat it.(3-5)

Coating may be applied to multiple range of oral solid dosage form, including tablets, capsules, multiparticulates and drug crystals. When coating composition is applied to a batch of tablets in a coating pan, the tablet surfaces become covered with a tacky polymeric film. Before the tablet surface dries, the applied coating changes from a sticky liquid to tacky semisolid and eventually to a non-sticky dry surface pans. The entire coating process is conducted in a series of mechanically operated acorn-shaped coating pans

International Journal of Pharmaceutical Research and Applications
Volume 8, Issue 1 Jan-Feb 2023, pp: 1811-1820 www.ijprajournal.com ISSN: 2249-7781

of galvanized iron stainless steel or copper. The smaller pans are used for experimental, developmental, and pilot plant operations, the larger pans for industrial production.[4-5]

Primary components involved in tablet coating

- Tablet properties
- Coating process
- Coating equipments
- Parameters of the coating process
- Facility andancillary equipments
- Automation in coating processes.[4-5]

Coating Process Design & Control

In most coating methods, when the tablets are being agitated in a pan, fluid bed, etc. at that timespraying on tablets by coating solution takes place. As the solution is being sprayed, a thin film is formed that adheres directly to each tablet. The coating may either be formed by a single application or may be built up in layers through the use of multiple spraying cycles.[2]

In pharmaceutical industry, rotating coating pans are often used. Firstly, uncoated tablets are placed in the pan, which is typically tilted at an angle from the horizontal, and then the liquid coating solution is introduced into the pan while the tablets are tumbling. By passing air over the surface of the tumbling tablets, the liquid portion of the coating solution is thenevaporated. In comparison, a fluid bed coater operates by passing air through a bed of tablets at a velocity sufficient to support and separate the tablets as individual units. Once separation takes place, then the tablets are sprayed with the coating composition.[3-9]

ENTERIC COATING NECESSARY:

1. After taking a typical supplement:

The tablet is swallowed and travels down the oesophagus to the stomach. In the stomach the tablet is churned and gyrated in highly acidic digestive Secretions with pH (1-4), for 45 minute to 2 hours. If there is anything left of tablet, it will be passed through the duodenum to the small intestine.

2. Fate of Uncoated Tablets

Stomach acid breaks down tablets to prematurely release active ingredients (enzyme).The highly acidic environment of the stomach destroys the majority of the enzyme's activities. If the tablet is of poor quality (contains Binder and fillers) the product may pass through boththe stomach and intestine with no absorption.

Primary Component Involved In Enteric Coated Tablets Formulation

- **Manufacture of Tablet core:**
- **Coating Composition:**

a) Polymers.
b) Plasticizer.
c) Solvent.
d) Colorant.

- **Coating process**

A) Coating Equipment

a) A coating pan.
b) A spraying system.
e) An air handling system.
d) A dust collector.
e) Process Parameter.

Composition of Enteric Coating

An enteric coating composition of tablets includes about 0.01% - 10% resin and about 0.01% - 10% polymer. The enteric coating composition may be a pharmaceutical, neutraceutical, fruit, vegetable, agriculture or industrial product to form an enteric coating on the substrate.[10]

Additives	Example
Resin	Shellac
Polymer	Alginate
Plastisizer	Triethyl citrate
Preservative	Sorbates
Detackifying agent	Monosterate
Lubricant	Palmitic acid
Colorant	FD &C lake yellow

Ideal properties of enteric coating material

- Resistance to gastric fluids
- Susceptible/permeable to intestinal fluid
- Compatibility with most coating solution components and the drug substrate
- Formation of continuous film

International Journal of Pharmaceutical Research and Applications
Volume 8, Issue 1 Jan-Feb 2023, pp: 1811-1820 www.ijprajournal.com ISSN: 2249-7781

 Nontoxic, cheap and ease of application Ability to be readily printed[5-7]

Polymers used for enteric coating Polymers	Dissolution pH
Shellac	7.0
Cellulose acetate pthalate	6.2
Poly(methacrylic-co-methyl Methacrylate	5.5-7.70
Cellulose acetate trimellitate	5.0
Poly(vinyl acetate pthalate)	5.0
Hydroxypropyl methyl cellulose pthalate(HPMCP)	4.5-5.5
Hypromellose acetate succinate	>5.5
Hypromellose phthalate	>5.5
Eudragit L100 -55	>5.5
Eudragit L30D-55	>5.5
Eudragit L100	>6.0
Eudragit L12,5	>6.0
Eudragit S-100	>7.0
Eudragit S12,5	>7.0
Eudragit FS30D	>7.0
Hydroxyl propylethyl cellulose pthalate	>4.5

Process of Coating[11-12]

Tablet coating takes place in a controlled atmosphere inside a perforated rotating drum. Once batch of tablets were loaded into the coating pan, preheat the tablets and allow time for dust and tablet flash to exit the pan. Angled baffles fitted into the drum and air flow inside the drum provides means of mixing the tablet bed. As a result, the tablets are lifted and turned from the sides into the centre of the drum, exposing each tablet surface to an even amount of deposited/sprayed coating. Once the temperature of the outlet air reaches 42°C to 46°C, usually within 15 minutes, spraying can begin.The spray guns create a fine mist of coating solution that dries just after it contacts the tablet. The liquid spray coating dried onto the tablets by heated air drawn through the tablet bed from an inlet fan. The air flow is regulated for temperature and volume to provide controlled drying and extracting rates, and at the same time, maintaining the drum pressure slightly negative relative to the room in order to provide a completely isolated process atmosphere for the operator.As the water evaporates, it leaves the solids behind to form a thin film on the tablet. The key to tablet coating is to get the surface slightly wet and immediately dry. Apply the coating in many short, fast exposures, not in long, slow exposures.Once the base coating is applied, you can increase the rate of solution addition and the pan speed proportionately.

International Journal of Pharmaceutical Research and Applications
Volume 8, Issue 1 Jan-Feb 2023, pp: 1811-1820 www.ijprajournal.com ISSN: 2249-7781

Typically, it takes about 20 minutes before increasing the spray rate and pan speed significantly.

Tablets that are very porous may require an initial spray rate that is slower than the average of 100 millilitres per minute per gun. Be sure to monitor spraying to see whether the spray pattern changes. If it does, there is likely a build-up of solids on the gun tips. Correct thisonly by cleaning the tips, which means stopping the spray and the pan. The enteric coating solution dries on the tablet surface because there is a constant supply ofhot air entering the drum and passing through the drum perforations into the bed of tablets. Over time, the film builds layer after layer of solids. After finished applying the solution and drying it, the tablets must cool. For coatings to adhere properly, the tablets must remain at a specific temperature, the solution must be applied at a consistent rate, and the motion of the tablets must be active yet tranquil. Disrupt any of these conditions, and this will produce a defective tablet.

Mechanism of Enteric Coated Tablets

ETP tablets are composed of three layers, a drug containing core tablet (rapid release function), the press coated swellable hydrophobic polymer layer (Hydroxy propyl cellulose layer (HPC), time release function) and an enteric coating layer (acid resistance function).[13]

The tablet does not release the drug in the stomach due to the acid resistance of the outer enteric coating layer. The enteric coating layer rapidly dissolves after gastric emptying and the intestinal fluid begins to slowly erode the press coated polymer (HPC) layer. Rapid drug release occurs when the erosion front reaches the core tablet since the erosion process takes a long time as there is no drug release period (lag phase) after gastric emptying. The duration of lag phase (drug release period) is controlled either by the weight or composition of the polymer (HPC) layer.

Methods used in manufacturing of tablet:

A) Direct compression

Direct compression is defined as the process by which tablets are compressed directly from powder mixture of API and suitable excipients. No pre-treatment of the powder blend by wet or dry granulation procedure is required. The advantage of direct compression include saving in energy, equipment, material and handling cost. The disadvantage include segregation problem, content uniformity problem and dust generation.

B) Wet Granulation Process

wet granulation. Wet granulation process simply involves wet massing of the powder blend with a granulating liquid, wet sizing and drying.

Important steps involved in the wet granulation

i) Mixing of the drug(s) and excipients.
ii) Preparation of binder solution.
iii) Mixing of binder solution with powder mixture to form wet mass. moist granules. Mixing of screened granules with disintegrant, glidant and lubricant.

Recent Trends In Tablet Coating Techniques

Electrostatic dry coating

An electrostatic dry powder coating process for tablets was developed for the first time by electrostatic dry powder coating in a pan coater system. The optimized dry powder coating process produces tablets with smooth surface, good coating uniformity and release profile that are comparable to that of the tablet cores. This novel electrostatic dry powder coating technique is an alternative to aqueous or solvent based coating process for pharmaceutical products. [14]

The electrostatic coating process is widely useful in food technology, paint technology, metal coatings, coating of living cells and coating of tablets as well as capsules. The principle of electrostatic powder coating states that spraying of a mixture of finely grounded particles and polymers onto a substrate surface without using any solvent and then heating the substrate for curing on oven until the powder mixture is fused into film [15]

Magnetically Assisted Impaction Coating (MAIC)

A Technique is developed for estimating the coating time in a magnetically assisted impaction coating (MAIC) device. The mixture of the host, guest and magnetic particles is assumed to stay in a fluidized state where the distribution of velocities is a Maxwell–Boltzman type. It is assumed that the collisions occurs among the particles are important for impinging the guest particles onto the surface of host particles, and thus forming a semipermanent coating on the surface of host particles. The coating time is depending on several parameters, including the number density of

International Journal of Pharmaceutical Research and Applications
Volume 8, Issue 1 Jan-Feb 2023, pp: 1811-1820 www.ijprajournal.com ISSN: 2249-7781

host particles, the diameter ratio of the host and guest particles, the height of the fluidized particle bed and the material properties of the host and guest particles. There is an optimal value of the bed height for which the coating time is a minimum. The coating time increases sharply the bed height is smaller and larger than the optimal value, and also when the diameter of host particles is increased.[16]

Various dry coating methods have been developed such as compression coating, plasticizer dry coating, heat dry coating and electrostatic dry coating. These methods generally allow for the application of high shearing stresses or high impaction forces or exposure to higher temperature for coating. The strong mechanical forces and the accompanying heat generated can cause layering and even embedding of the guest particles onto the surface of the host particles. Many foods and pharmaceutical ingredients, being organic and relatively very soft, are very sensitive to heat and can quite easily be deformed by severe mechanical forces. Hence, some soft coating methods that can attach the guest (coating material) particles onto the host (material to be coated) particles with a minimum degradation of particle size, shape and composition caused by the buildup of heat are the best candidates for such applications. The magnetically assisted impaction coating (MAIC) devices can coat soft organic host and guest particles without changing in the material shape and size. Although there is some heat generated on a minute level due to the collisions of particles during MAIC, but it is negligible. This is an additional advantage when dealing with temperature sensitive powders such as pharmaceuticals [15].

Magnetically Assisted Impaction Coating (MAIC) is being developed to improve the effectiveness of mixing powders with nano-sized particles without the aid of a solvent or heat. In general, uniform mixing of nano-sized.

3D printing

3D printing is nowadays an innovative formulation technology. It is also a cheap and easy method for including a polymer for controlling the release of drugs without using classical coating technologies like coating pan or fluidized bed. An extruder device can be used to prepare polymer filaments loaded with one or more drugs adequate for fuseddeposition 3D printing. 3D printer with more than one nozzle permits the manufacturing of different solid devices, such as multilayer or coated devices.[17]Consequently, it may be possible to use hot melt extrusion to include coating polymers in filaments that can be used for printing around 3D printed cores.[18]

Microencapsulation

Microencapsulation allows for the coating of particles (liquid, solid, semisolid or gases) with polymeric coating materials. They can be manufactured using several methods. The most common methodology is to induce coacervation or separation of macromolecules around the cores via a stimulus like temperature change or solvent change, etc.Particles that are able to form a coating are dispersed in a macromolecule solution and a stimulus is used to induce coacervation. The resulting coacervate droplets stay on the particle surface, forming the coating. Finally, this layer must be treated so that it becomes rigid.

Marketed Preparations Of Enteric Coated Tablets:

Brand name	Generic name	Indication
Protonix	Pantoprazole	Heart burn, acid reflux
Aciphex	rabeprazole	Duodenal ulcers
Pritosec	omeprazole	Reflux esophagitis
Nexium	esomeprazole	Erosive esophagitis
Prevacid	lansoprazole	Indigestion, GORD
Endicer	Diclofenac	inflammation,arthritis
Ecosprin 75	Aspirin	Chest pain
Deltacortil	Corticosteroid	Allergic reactions
Lipothiamine	Thiamine tetrahydrofurfutrl disulphide	Heart disease
GreenTea +piperine	Polyphenols	Cell proliferation
Tru Niagen	Nicotinamide riboside	Rejuvenate cell production

International Journal of Pharmaceutical Research and Applications
Volume 8, Issue 1 Jan-Feb 2023, pp: 1811-1820 www.ijprajournal.com ISSN: 2249-7781

Nootropics depot	Nicotinamide momonucleotide	Wakefulness
Chymoral forte	Chymotrypsin + trypsin	Pain and swelling
Wobenzym plus	Domperidone &pantoprazole	Indigestion & stomach pain
Nusam 200	S-Adenosyl-L-metionine	Liver problems
EC-NAPROSYN	Naproxen	Inflammation
Ecotrin	Aspirin	Heart attack
Denosyl	S-Adenosyl methionine	Depression, anxiety
Zymactive	Microcrystalline Cellulose	Arthritis
Dulcolax	Biscodyl laxative	Constipation
MINOZ 50	Minocycline dihydrochloride	Bacterial infections
Inderal LA	Proparnolol	Heart problems
Testopel pellets	Testosterone	Low testosterone
Omeprazole delayed release	Omeprazole	Stomachproblems
Astrix capsules	Aspirin	Systemicembolism
Doryx capsule	Doxycycline	Urinary tract infection
Kadina capsule	Morphine sulphate	Pain in cancer patients
Itraconazole enteric coated pellets	Itraconazole	Fungal infections
Bontril SR	Phendimetrazine	Obesity symptoms
Brexin LA	Chlorpheniramine	Common cold
Compazine	Prochlorpepazine	Nausea, vomiting
Dilgard XL 180	diltiazen hydrochloride	High blood pressure
Cardizem CD 360 mg	Diltiazen	High blood pressure

Advantages of Enteric Coating

Protect the drug from the stomach

 Protect the acid liable drugs from the gastric fluid e.g. enzymes and certain antibiotics

 Coatings are necessary for tablets that have an unpleasant taste, and a smoother finish makes large tablets easier to swallow.(17)

 Forbid gastric distress or nausea due to irritation from a drug, e.g. sodium salicylate.[18]

 Deliver drugs intended for local action in the intestines, e. g. intestinal antiseptics could be delivered to their site of action in a concentrated form.[19]

Disadvantages Of Enteric Coating

1. Requires the expertise of highly skilled technician.[20]
2. This process is tedious and time-consuming.(21)

Applications of enteric coating

- **Reduced GI toxicity**

To overcome the Gl adverse events, an enteric-coated formulation of the sodium salt of MPA was developed. (EC mycophenolate sodium or EC-MPS. Myfortic"). The commercial product is a delayed release tablet with a hypromellose phthalate coating. Pharmacokinetic studies in patients confirmed the delayed release, and the time of peak plasma concentration of MPA was 1.5-2.75 h after oral administration of MPS-later than that of MMF (T 0.5-1b).

At standard doses, EC-MPS was able to consistently achieve AUC >30 ug h/mL., which is believed to be the level needed for efficacy. Both

International Journal of Pharmaceutical Research and Applications
Volume 8, Issue 1 Jan-Feb 2023, pp: 1811-1820 www.ijprajournal.com ISSN: 2249-7781

efficacy and adverse events were reported to be similar for equivalent doses of MMF and EC-MPS (for active moiety mycophenolate. 1000 mg of MMF is equivalent to 720 mg of MPS). Since pharmacokinetic analysis showed that EC-MPS reached statistically higher plasma concentrations at equi- molar doses, and it was not associated with an increase in adverse events, EC-MPS may provide increased tolerability relative to systemic exposure, thus providing more patients with therapeutic concentrations. It is difficult to quantify Gl adverse events following transplantation due to many confounding factors such as the stress of surgery, data collection techniques, concomitant medications, and high prevalence of Gl events even without MPA treatment. One study where patients were switched from MMF to EC-MPS did indicate a reduction in severity of Gl events for EC-MPS. Other reports showed similar outcomes after the switching from MMF to MPS. In heart trans- plantation, there was significant difference in dose reduction of MMF 42.1% versus MPS 26.9% ($p < 0.05$). Con- flicting reports have been published for liver trans- plants.. These authors concluded that it is beneficial to convert MMF to MPS.

- **Targeting to Specific Regions of the GI Tract**

For some drugs, targeting the release of active to the small. intestine can offer therapeutic benefits. Cysteamine is one drug that has been reported to give the highest exposure when targeted to release in the small intestine compared to the stomach or cecum. However, site-specific delivery to the proximal small intestine may be difficult due to the perceived slow in vivo dissolution of dosage forms once the enteric coat disintegrates. As early as the 1970s, it was suggested to use effervescent formulations with an enteric coat to get rapid disintegration in the proximal small intes- tine Indomethacin and erythromycin are two exam- ples of the many drugs that have their principal absorption site in the proximal small intestine. Formulating these drugs in an enteric product must be done carefully to ensure that the dosage form is delivered intact from the stomach and then quickly made available for absorption. One technique that has been recommended in these instances for good reproducibility and low intersubject variability is to enteric coat formulations having diameters no greater than 5mm.

EVALUATION OF GRANULES [22]

Measurement of the angle of repose

The angle of repose was determined by the funnel method. The determination of angle of repose by this method is referred to as static angle of repose. Angle of repose is an indirect method of quantifying powder flow ability; because of their relationship with inter particle cohesion. A static heap will slide when the angle of inclination is large enough to overcome frictional forces and stop when gravitational forces balance the forces. The sides of heap will make an angle with horizontal which is called angle of repose.[23] Powder is poured onto the centre of the dish from the funnel that can be raised vertically until the maximum cone height (h) is obtained.

The angle of repose can be calculated by the given formulae.

$\alpha = \tan^{-1}(h/r)$,

where h is height of pile and r is radius of pile.This was done thrice, from that average angle of repose and standard deviation was calculated.

- **Pore/Bulk density**

The apparent true density (ρb) was measured by pouring the pre weighed (M) blend into a graduated cylinder. The bulk volume (Vb) of the blend was determined by this method. Then the true density was determined by the given below formulae.

$\rho b = M/Vb$

This was done thrice, from that average true density and standard deviation was calculated.

- **Tap density**

  The measured cylinder containing a known mass (M) of blend was tapped for a fixed time, and the minimum volume (Vt) occupied in the cylinder was measured. The tapped density was calculated by the formulae mentioned below.

  Tap density = M/Vt

  This was done thrice, from that average tap density and standard deviation was calculated.

- **Porosity[24]**

  The porosity of voids and of the powder is defined as the ratio of void volume to the bulk volume of the packaging.

  $E = (Vb - Vp)/Vb = 1 - (Vp/Vb)$

EVALUATION OF CORE AND COATED TABLETS

The core and coated tablets were evaluated for hardness, friability, weight variation, disintegration time, thickness, drug content and in vitro release studies.

International Journal of Pharmaceutical Research and Applications
Volume 8, Issue 1 Jan-Feb 2023, pp: 1811-1820 www.ijprajournal.com ISSN: 2249-7781

- **Hardness**

The tablet crushing strength was measured by using Monsanto tablet hardness tester. A tablet is placed between the anvils and the crushing strength, which causes the tablet to break, was recorded.[25]

- **Friability**

Tablet strength was tested by Roche friabilator. Twenty tablets were accurately weighed and placed in the friabilator and operated for 100 revolutions in 4 min. The tablets were dedusted and the percentage weight loss was calculated by reweighing the tablets. The tablets that loose less than 1% weight were considered to be compliant.

- **Weight variation [26]**

In weight variation, twenty tablets were selected at random and average weight was determined using an electronic balance. Tablets were weighed individually and compared with average weight.

- **Disintegration time [25]**

Disintegration time was determined using the disintegration apparatus USP in 0.1N HCl for 2 hrs. and then in phosphate buffer pH 6.8 for 1 hour maintaining the temperature at 37 ± 2°C.

- **Thickness [26]**

The thickness of the tablet was measured by using vernier calipers.

- **Drug content studies [26]**

Ten tablets were weighed individually and powdered; an amount equivalent to 5 mg of drug was taken and 50 ml of 95% ethanol was added and was shaken for 30 minutes. Sufficient ethanol (95%) was added to produce 100 ml. It was centrifuged and suitable volume of the supernatant liquid equivalent to 0.5 mg of drugwas pipette out and diluted to 50ml with 95% ethanol. The solution was filtered (through 0.45 µm). Drug content was measured at 236 nm using UV/Visible single beam spectrophotometer.

Defects Related to Tabletting Process

Capping

'Capping' is the term used, when the upper or lower segment of the tablet separates horizontally, either partially or completely from the main body of a tablet and comes off as a cap, during ejection from the tablet press, or during subsequent handling. Capping is usually due to the air–entrapment in a compact during compression, and subsequent expansion of tablet on ejection of a tablet from a die.[27]

- **Lamination**

'Lamination' is the separation of a tablet into two or more distinct horizontal layers. Lamination is due to air–entrapment during compression and subsequent release on ejection. The condition is exaggerated by higher speed of turret.[28]

- **Chipping**

'Chipping' is defined as the breaking of tablet edges, while the tablet leaves the press or during subsequent handling and coating operations. Chipping is caused due to incorrect machine settings, specially mis-set ejection take-off.[29]

- **Sticking**

'Sticking' refers to the tablet material adhering to the die wall. Filming is a slow form of sticking and is largely due to excess moisture in the granulation. Sticking takes place when improperly dried or improperly lubricated granules were used.(30)

- **Picking**

'Picking' is the term used when a small amount of material from a tablet is sticking to and being removed off from the tablet-surface by a punch face. The problem is more prevalent on the upper punch faces than on the lower ones. The problem worsens, if tablets are repeatedly manufactured in this station of tooling because of the more and more material getting added to the already stuck material on the punch face.Picking is of particular concern when punch tips have engraving or embossing letters, as well as the granular material is improperly dried.[31]

- **Mottling**

'Mottling' is the term used to describe an unequal distribution of colour on a tablet, with light or dark spots standing out in an otherwise uniform surface. One cause of mottling may be a coloured drug, whose colour differs from the colour of excipients used for granulation of a tablet.

II. LIMITATIONS

The reliability and delivery efficiency is doubtful due to presence of wide range of pH values and different enzymes present in the GI tract which is encountered by the drugs before reaching the target site.[32]

International Journal of Pharmaceutical Research and Applications
Volume 8, Issue 1 Jan-Feb 2023, pp: 1811-1820 www.ijprajournal.com ISSN: 2249-7781

III. OBJECTIVE

The present study attempts to give an insight into the gastro-resistant drug delivery systems, and enteric coated tablets, in particular. Recently, these have attracted the interest of many formulators due to their advantages over the conventional drug delivery systems. The study provides an overview of the recent advances that have taken place in this arena.[33]

IV. CONCLUSION

From the above review, we can conclude that tablets are made enteric-coated for avoiding the first pass metabolism, gastric irritation and degradation and to direct the drug to the target intestines. Enteric coating protects the stomach against drugs which causes gastric irritation. Enteric coating protects the drug which is unstable in gastric fluids. The manufacturing defects of tablets include capping, lamination, chipping, picking and mottling. Enteric coated tablets were evaluated for hardness, weight variation, thickness, friability, appearance, dissolution test and disintegration test. This dosage form is preferred as it is very convenient and easy to formulate, cost-effective and does not require high cost equipments. For that reason, this dosage form has been gaining so much attention nowadays.

REFERENCES

[1]. Anil KP and Betty P, Colon Targeted Drug Delivery Systems: A Review on Primary and Novel Approaches, Oman Medical Journal, 2010; 5(02):70-78.
[2]. Sing DH, Roychowdhury S, Verma P, Bhandari V: A review on recent advances of enteric coating IOSR Journal of pharmacy, 2012; 2: 2250-3013.
[3]. Lachman L, Lieberman HA, Joseph LK. The Theory and Practice of Industrial Pharmacy. Varghese Publishing House; Mumbai; Third Edition: 297-321.
[4]. Lachman L, Liberman H, Kanig J. The Theory and Practice of Industrial Pharmacy; Third Edition: 293-345, 346-373.
[5]. Aulton M. Pharmaceutics: The Science of Dosage Form Design.International Student Edition: 304-321, 347-668
[6]. Vyas S, Khar R. Controlled Drug Delivery Concepts and Advances; First Edition: 219-256.
[7]. Ansel H, Allen L, Jr. Popovich N. Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems; Eighth Edition: 227-259.
[8]. Remington J. Remington: The Science and Practice of Pharmacy; 2(19): 1615-1641.
[9]. American Pharmaceutical Reviews 2001; 4(3): 28-35.
[10]. Sanga D, Tara C: Formulation, development and evaluation of enteric coated tablet of sodium valproate by using wet granulation method, Am. J. Pharma Tech., 2013; 3(2): 6-18.
[11]. Hita V, Singh R, Jain SK. Colonic targeting of metronidazole using azo aromatic polymers, development and characterization. Drug Del, 1997; 4: 19-22.
[12]. Mounica P, Pavani S and Mounica R:A review on recent advances in enteric coating and enteric polymer, World Journal of Pharmaceutical Research, 2018; 7(2): 475-495.
[13]. Vachhani SR, Patel JJ, Patel D, Prajapati ST and Patel CN, J. Chem. Pharm. Res., 2010; 2(2): 57-64.
[14]. Qiao M. et al A Novel Electrostatic Dry Powder Coating Process for Pharmaceutical Dosage Forms: Immediate Release Coatings for Tablets. European Journal of Pharmaceutics and Biopharmaceutics, 2010; (3): 304- 310.
[15]. Pawar A. et al Advances in Pharmaceutical Coatings. International Journal of ChemTech Research, 2010; 2(1): 733 – 737.
[16]. Patentgenius, Phoqus Pharmaceutical Limited Patents. Patentgenius, 2011;3(9):[Cited2012Aug.21],Availablefrom http://www.patentgenius.com/assignee/PhoqusPharmaceuticals Limited.html
[17]. Goole, J., Amighi, K., 2016. 3D printing in pharmaceutics: a new tool for designing customized drug delivery systems. Int. J. Pharm. 499, 376–394.
[18]. Goyanes, A., Wang, J., Buanz, A., Martínez-Pacheco, R., Telford, R., Gaisford, S., Basit, A.W., 2015. 3D printing of medicines: engineering novel oral devices with unique design and drug release characteristics. Mol. Pharm. 12, 4077–4084.

[19]. Aurora J, Talwar N and Pathak V. Colonic Drug Delivery Challenges and Opportunities – An Overview. European Gastroenterology Review,2006; 1-6.
[20]. Sushama P, Suryaprakash M, Pooja H, Nitin R, Sharayu B, Dr.Nilesh MKe: A detail understanding of enteric coated tablet: manufacturing and evaluation, European Journal of Pharmaceutical and Medical Research, 2016; 3(4): 135-144.
[21]. Gobinath T, Kamalakkannan V, Sambathkumar R: Formulation and evaluation of enteric coated tablet of pentoprazole, Journal of Chemical and Pharmaceutical Sciences, 2014; 7(3): 176-184.
[22]. Ansel H, Allen L, Jr. Popovich N. Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems; Eighth Edition, 227-259.
[23]. A detail understanding of enteric coated tablet: manufacturing and evaluation by Sushama Pole, Suryaprakash Maurya, Pooja Hasnale, Nitin Rathod, Sharayu Bendale, Dr. Nilesh M. Khutle Assistant Professor, Department of Pharmaceutics, Dr. L.H. Hiranandani College of Pharmacy, Ulhasnagar, Maharashtra, India. Pin-421003
[24]. Vidyadhara S, Chowdary YA, Murthy TEGK, Rao MV, Reddy KNK. Influence of electrolytes on controlled release of Ambroxol Hydrochloride from methocel matrix tablets. The Pharma Review 2006; June: 101-104.
24.Jaimini M, Rana AC, Tanwar YS. Formulation and Evaluation of Famotidine Floating Tablets. Current Drug Delivery 2007; 4: 51-55.
[25]. N. Damodharan, V. Manimaran and B. Sravanthi, Formulation development and evaluation of delayed release doxycycline tablets, International Journal of Pharmacy and Pharmaceutical Sciences, 2(1), 2010.
[26]. Patil Ajit, Payghan Santosh and Disouza John, Formulation and Evaluation of Enteric coated tablets of Azithromycin dihydrate, International Journal of ChemTech Research, 3(3), 2011, 1479-1484.
[27]. D. Raju, J. Padmavathy, V. Sai Saraswathi, D. Saravanan and I. Aparna Lakshmi, Formulation and development of enteric coated tablets of prednisolone as a colon targeted drug delivery, IJPSR, 2(3), 2011, 685-690.
[28]. Raju D, Padmavathy J, Sai SV, Saravanan D and Aparna LI Formulation and development of enteric coated tablets of prednisolone as a colon targeted drug delivery, International Journal of Pharmaceutical Sciences and Research, 2011; 2(3): 685-690.
[29]. Aulton M. Pharmaceutics: The Science of Dosage Form Design. International Student Edition: 304-321: 347-668.
[30]. Patil A, Payghan S and Disouza J, Formulation and Evaluation of Enteric coated tablets of Azithromycin dihydrate, International Journal of Chem Tech Research, 2011; 3(3): 1479-1484.
[31]. Leon Lachman, Herbert A, Liberman, Kaing Joseph L., The theory and practice of industrial pharmacy, Varghese publishing house, Bombay, 3rd edition, 293-295.
[32]. Gazzaniga A, Iamartino P, Maffino G and Sangalli ME, Oral delayed release system for colonic specific drug delivery, Int J Pharm, 1994; 108: 77-83.
[33]. Aurora J, Talwar N and Pathak V. Colonic Drug Delivery Challenges and Opportunities – An Overview. European Gastroenterology Review 2006: 1-6.
[34]. Vachhani Savan R, Patel Jatin J, Patel Dipen, Prajapati ST and Patel CN, J. Chem. Pharm. Res., 2(2), 2010, 57-64